

**REMARKS**

Applicant respectfully requests reconsideration.

Claims 1-5, 19 and 25-38 were previously pending in this application. Claims 1-5, 26, 37 and 38 were withdrawn from consideration.

By this amendment, Applicant is canceling claims 19, 26, and 27 without prejudice or disclaimer. Claims 25, 28, 29, 31, 33 and 34 have been amended without prejudice or disclaimer.

As a result, claims 25 and 28-36 are pending for examination with claim 25 being an independent claim. No new matter has been added.

**Rejections under 35 U.S.C. §112**

Claims 19, 25, and 27-36 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has canceled claims 19, 26, and 27 without prejudice or disclaimer, thereby obviating the rejection of these claims under 35 U.S.C. §112. Applicant notes that claim 26 had been withdrawn by the Examiner, but a rejection of claim 26 was also included on page 3 of the office action.

Claim 25 was rejected, because the phrases “a method of recovering the blood glucose level history of a patient,” and “obtaining a cell distribution profile by sorting a plurality of the intact cells based on the amount of glycated hemoglobin...and determining the patient’s glucose level history based on the cell distribution profile” were allegedly unclear.

Applicant respectfully disagrees. However, Applicant has amended claim 25 to recite a “method for obtaining information about the blood glucose level history of a patient diagnosed with diabetes.” Claim 25 as amended also recites sorting a “plurality of intact red blood cells to measure an amount of glycated hemoglobin for each cell and generating a cell distribution profile that represents the number of red blood cells as a function of the amount of glycated hemoglobin per cell.” Amended claim 25 further recites “dividing the cell distribution profile into a series of bins each containing a number of cells representing a time interval and calculating a change in the amount of glycated hemoglobin for each bin, thereby obtaining information about the blood glucose

level history of the patient for each time interval represented by the series of bins.” Applicant respectfully submits that these amendments address the rejections of claim 25 by i) clarifying that information is obtained from a cell distribution profile, ii) reciting how the cell distribution profile is obtained, and iii) reciting how information about the blood glucose level history of the patient is obtained from the cell distribution profile.

Claim 33 was rejected, because it was allegedly “unclear what parameters are to be considered ...” In response, Applicant has amended claim 33 to clarify that the information obtained about the blood glucose level history of the patient is used to assist in determining whether the patient has Type I, Type II, or gestational diabetes, as explained in the specification, for example, on pages 38-39.

Claim 34 was rejected, because it was allegedly unclear “what the parameters of a treatment regime are based.” In response, Applicant has amended claim 34 to clarify that an anti-diabetic treatment regimen for the patient is determined based on the information obtained about the blood glucose level history of the patient, as explained in the specification, for example, on pages 43-44.

Accordingly, reconsideration and withdrawal of these rejections under 35 U.S.C. §112 is respectfully requested.

#### Rejections Under 35 U.S.C. §102

Claim 19 was rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,540,895 (Spence et al.). Claim 19 was also rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,784,981 (Roche et al.).

Applicant has canceled claim 19 without prejudice or disclaimer. Accordingly, reconsideration and withdrawal of these rejections under 35 U.S.C. §102 is respectfully requested.

#### Rejections Under 35 U.S.C. §103

Claims 25 and 27-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over 6,540,895 (Spence *et al.*) in view of U.S. Patent No. 4,835,097 (Saunders).

In response, Applicant submits that Spence *et al.* and Saunders, taken alone or in combination, fail teach or suggest a method for obtaining information about the blood glucose level

history of a patient by sorting a plurality of intact red blood cells to measure an amount of glycated hemoglobin for each cell, generating a cell distribution profile that represents the number of red blood cells as a function of the amount of glycated hemoglobin per cell, and dividing the cell distribution profile into a series of bins each containing a number of cells representing a time interval and calculating a change in the amount of glycated hemoglobin for each bin, thereby obtaining information about the blood glucose level history of the patient for each time interval represented by the series of bins, as claimed in amended claim 25. In addition, Applicant submits that Spence *et al.* and Saunders, taken alone or in combination, fail to provide either a predictable solution or a reasonable expectation of success for obtaining information about the blood glucose level history of a patient as claimed in amended claim 25.

In particular, Applicant submits that Spence *et al.* fails to provide any teaching that relates to obtaining information about the blood glucose level history of a patient. In addition, Applicant submits that Spence *et al.* and Saunders, taken alone or in combination, fail to teach or suggest obtaining information about the blood glucose level history of a patient based on the amount of glycated hemoglobin in intact red blood cells by generating a cell distribution profile that represents the number of red blood cells as a function of the amount of glycated hemoglobin per cell, and dividing the cell distribution profile into a series of bins each containing a number of cells representing a time interval and calculating a change in the amount of glycated hemoglobin for each bin, thereby obtaining information about the blood glucose level history of the patient for each time interval represented by the series of bins.

Accordingly, reconsideration and withdrawal of these rejections under 35 U.S.C. §103 is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

By Pat R.H. Waller

Patrick R.H. Waller  
Registration No.: 41,418  
WOLF, GREENFIELD & SACKS, P.C.  
Federal Reserve Plaza  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
(617) 646-8000